

REMARKS

Claims 1-32 are pending. No claims have been added, canceled or amended herein. Accordingly, claims 1-32 will remain pending and under examination upon consideration of this Communication.

In view of the arguments set forth below, applicants maintain that the Examiner's rejections made in the August 13, 2004 Office Action have been overcome, and respectfully request that the Examiner reconsider and withdraw same.

The Claimed Invention

The instant invention provides methods of delivering an antigen to a class I MHC receptor to induce immunity against the antigen in a subject having a disease wherein the antigen is associated with the presence of the disease in the subject. The claimed invention is based on applicants' surprising discovery that antigen-filled particles will bind to ligand-binding antigen-presenting cells (APCs), permitting the APC phagolysosomes to ingest the Ag-particles to facilitate transfer of the ingested antigen from the phagolysosomes into the cytoplasm.

Rejections Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 1-32 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement because the rejected claims allegedly contain subject matter which was not described in the specification in such a way as to allow one skilled in the relevant art to which it pertains to make and/or use the invention commensurate in scope with the claims.

In response, applicants respectfully traverse the Examiner's rejection for the reasons of record and for the additional reasons set forth below.

The test for enablement is whether one skilled in the art could, at the time of the invention, make and use the claimed invention based

on the disclosure and information known in the art without undue experimentation. Applicants maintain that the claimed invention satisfies the test for enablement, and that the Examiner has not set forth sufficient grounds for concluding otherwise.

In support of the rejection, the Examiner asserts that undue experimentation would be required to practice the claimed methods with a reasonable expectation of success, absent a specific and detailed description of how to practice the claimed methods and absent working examples providing evidence that the claimed methods are effective.

Applicants disagree with the Examiner's position. The cited references, Grufman et al., Sala et al. (2001), and Sala et al. (2002) fail to support the Examiner's position that the claims are not enabled in light of the specification or that the state of the art is unpredictable. Grufman fails to teach the claimed method of priming APCs, but rather only teaches incubation of dendritic cells and an antigen in culture media. La Sala (2001 and 2002) teach exposure of dendritic cells to *extracellular* ATP via incubation while the instant invention involves an increase of *intracellular* ATP following phagocytosis of the Ag/ATP-filled particle. The Examiner asserts that there is no difference between extracellular and intracellular ATP because ATP is an intracellular messenger. Applicants assert, however, that the *different methods of introduction* of the ATP in La Sala and the instant invention are evidence of a functional difference between the references and the claimed methods. Therefore, contrary to the Examiner's position, there is no suggestion in the cited references that applicants' methods would fail to produce APCs capable of inducing a TH-1 response *in vivo*.

Furthermore, applicants maintain that the specification discloses a working example of the claimed methods. The applicants direct the Examiner's attention to, *inter alia*, pages 32-35 of the specification. Specifically, the specification discloses a procedure for loading an antigen into red blood cell ghosts,

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delivering the antigen to a Class I MHC receptor, and inducing of cytotoxic CD8 lymphocytes. The results of this procedure are confirmed by the experimental data set forth in Table 1. Therefore, applicants maintain that one skilled in the art would have a reasonable expectation of success in practicing the claimed methods.

In view of the above remarks, applicants maintain that claims 1-32 satisfy the requirements of U.S.C. §112, first paragraph.

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Summary

In view of the remarks made herein, applicants maintain that the claims pending in this application are in condition for allowance. Accordingly, allowance is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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4/10/04
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